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FROM : Oleg F. Kaplun, Esq.
Fay Kaplun & Marcin, LLP

DATE : October 2, 2007

SUBJECT : Oncology
U.S. Patent Appln. Serial No. 09/838,618
for *Catheter Slit Valves*
Inventor(s): Haarala et al.
Our Ref.: 10123/01101

NUMBER OF PAGES INCLUDING COVER : 13

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Please see attached.

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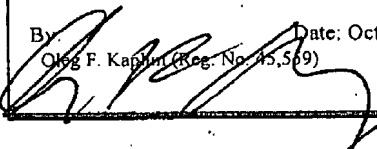
Attorney Docket No. 10123 - 01101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Haarala et al.
Serial No. : 09/838,618
Filed : April 19, 2001
For : CATHETER SLIT VALVES
Group Art Unit : 3753
Examiner : Craig M. Schneider
Confirmation No.: 3578

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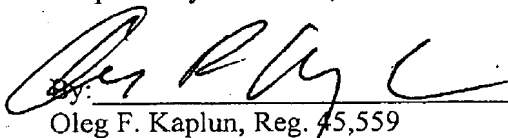
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| By:  Oleg F. Kaplun (Reg. No. 45,559) | Date: October 2, 2007 |

TRANSMITTAL

Transmitted herewith please find a Reply Brief in response to the Examiner's Answer mailed on August 3, 2007 and to the Appeal Brief filed June 19, 2007, for filing in the above-identified application. No fees are believed to be required. The Commissioner is hereby authorized to charge any additional required fees to the **Deposit Account of Fay Kaplun & Marcin, LLP No. 50-1492**. A copy of this paper is enclosed for that purpose.

Respectfully submitted,

Dated: October 2, 2007


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OCT 02 2007

PATENT

Attorney Docket No.: 10123 - 01101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

Haarala et al.

Serial No.: 09/838,618

Filed: April 19, 2001

For: CATHETER SLIT VALVES

Confirmation No.: 3578

Group Art Unit: 3753

Examiner: Craig M. Schneider

**Board of Patent Appeals and
Interferences**

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REPLY BRIEF UNDER 37 C.F.R. § 41.41

In response to the Examiner's Answer mailed on August 3, 2007 to the Appeal Brief filed June 19, 2007, and pursuant to 37 C.F.R. § 41.41, Appellants present this Reply Brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 43 - 46 in the final Office Action dated November 14, 2006 as clarified in the Examiner's Answer mailed June 19, 2007. The appealed claims are set forth in the attached Claims Appendix.

1. Grounds of Rejection to be Reviewed on Appeal

- I. Whether claims 43 - 44 and 61 are unpatentable under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 3,303,847 to Eaton.
- II. Whether claims 43 - 44 and 46 are unpatentable under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 3,718,140 to Yamauchi.
- III. Whether claim 45 is unpatentable under 35 U.S.C. § 103(a) as obvious over Eaton in view of U.S. Patent No. 5,798,018 to Engelson et al. ("Engelson").
- IV. Whether claim 46 is unpatentable under 35 U.S.C. § 103(a) as obvious over Eaton in view of Yamauchi.

2. Argument

- I. The Rejection of Claims 43 - 44 and 61 Under 35 U.S.C. §102(b) over Eaton (U.S. Patent No. 3,303,847) Should be Reversed.

In the Final Office Action, claims 43 - 44 and 61 were rejected under 35 U.S.C. 102(b) as anticipated by Eaton. *11/14/06 Office Action*, p. 3. Eaton describes a disposable container-applicator for liquids and fluid materials adapted to hold and dispense liquids or fluid materials into various openings of the human body. *Eaton*, col. 1, ll. 9-13. The container-applicator includes a "collapsible or squeezable tube" which opens only when the body portion 1 is physically deformed by external force applied thereto and which remains closed at all times when no manual pressure is applied. *Id.*, col. 3, ll. 65-70. Specifically, Eaton states that "pressure applied to the body portion 1 will cause the slits 8 and 9 of the flexible catheter to part slightly." *Id.* Eaton further states that, "when the container is not subjected to [manual] pressure, such [an] opening will remain closed sufficiently tightly to retain the contents of the container-applicator against the force of gravity." *Id.*, col. 3, l. 73 - col. 4, l. 1. This situation is the only one in which Eaton contemplates fluid pressure against the slits 8 and 9 (*i.e.*, when the container-applicator is held with the opening facing downward) and the valve is designed to remain closed under these conditions.

Claim 43 recites a device comprising "an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter" and "a compound slit extending from a generally

hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen, the compound slit being biased toward a closed position and opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter.”

In the final rejection, the Examiner stated that the “slit of Eaton is biased closed and opens due to [a] difference in pressure between the lumen and the ambient.” *11/14/06 Office Action*, p. 3. The Examiner further stated that Appellants have misunderstood the Eaton reference and asserted that the valve of Eaton opens when the container is squeezed because this increases a fluid pressure within the container. *Id.*, p. 6.

However, it is respectfully submitted that Eaton includes no description or suggestion of the Examiner’s assertion and, in fact, includes no mention of *fluid* pressure in any way influencing the state of the valve. Furthermore, Appellants submit that the direct statement in Eaton that the slits part slightly when the container is squeezed describes a mechanical deformation of the valve due to the squeezing and not any fluid pressure activated valve behavior which is nowhere described. It is respectfully submitted that any suggestion that this is a pressure activated valve is being read into the patent in hindsight by the Examiner. The mechanical deformation is evidenced from the description of the flexibility of the material from which the container-applicator is made. Specifically, due to the material properties, the opening remains closed to retain the contents of the container-applicator against gravity induced fluid pressure and opens slowly when manual pressure is applied to the body portion 1. Furthermore, Eaton nowhere implies that fluid pressure is used to part the slits as Eaton explicitly discloses a direct relationship between the material and the slits parting by reciting the “slight pressure applied to the body portion 1 will cause the slits or cuts 8 and 9 of the flexible catheter to part slightly.” *Eaton*, col. 3, ll. 67-69. At no point does Eaton state or suggest that the manual pressure increases a fluid pressure which, in turn, forces the slits to part.

The Examiner further asserted that the Appellants cited a section of Eaton that states fluid pressure opens the slit valve. *8/3/07 Examiner’s Answer*, p. 5. It is respectfully submitted that every section of Eaton cited by the Appellants is cited in its entirety and has been in no way misleadingly quoted. It is respectfully stated that Eaton nowhere states or suggests that fluid pressure opens the slit valve. Specifically, with reference to the sections cited by the Appellants, every section concerns a *manual* deformation of the slit valve. Furthermore, it is respectfully submitted that the Examiner has never shown a single statement in Eaton supporting his contention that fluid pressure opens the slit valve to contradict the direct statement in Eaton that pressure applied to the body portion 1 causes the slits to part slightly. *Eaton*, col. 3, ll. 65-70. Thus, it is submitted that Eaton never states or implies that fluid pressure is responsible for the

parting of the slits which opens the valve.

Thus, it is respectfully submitted that Eaton does not disclose or suggest a compound slit "opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter," as recited in claim 43 and Appellants respectfully request that the Board overturn this rejection of claim 43 and claims 44 and 61 which depend directly therefrom.

Claim 61 recites a compound slit configured so that "when the fluid pressure outside the catheter exceeds the fluid pressure within the lumen by a second predetermined amount, the flaps flex into the lumen to allow fluid outside the catheter to enter the lumen." In the final rejection of claim 61, the Examiner stated that the "slit of Eaton is also configured to inherently allow the flaps to flex into the lumen based on a predetermined pressure difference between the ambient pressure and the pressure inside the lumen." *11/14/06 Office Action*, p. 3. However, as discussed above, the opening of Eaton is not based on a difference in fluid pressure and in any case no opening of the slits inward is disclosed in Eaton under any circumstances. That is, any opening of the valve of Eaton by the slits flexing into the lumen represents a failure of the structure (*i.e.*, behavior directly contradicting the purpose for which it was designed). Because the slits of Eaton open only when manual pressure is applied to the body to mechanically deform the opening, the container-applicator is designed to only open in a predetermined direction. The only plausible way for the slits of Eaton to flex into the lumen is to apply mechanical force to the end of the valve or to apply considerable vacuum force to de-pressurize the body 1 and either of these possibilities is simply speculative and likely to represent a failure of the device. However, this is nowhere suggested and it is unclear whether the container of Eaton would survive such an operation or what purpose this would serve. That is, Eaton does not disclose the use of the container-applicator for fluid flow from the ambient into the lumen. In fact, Eaton shows that the container is filled through an open end 2 which is later sealed. *Eaton*, col. 3, ll. 22-28.

Thus, it is respectfully submitted therefore that Eaton does not disclose or suggest "a compound slit configured so that "when the fluid pressure outside the catheter exceeds the fluid pressure within the lumen by a second predetermined amount, the flaps flex into the lumen to allow fluid outside the catheter to enter the lumen," as recited in claim 61 and Appellants respectfully request that the Board overturn this rejection of claim 61.

II. The Rejection of Claims 43 - 44 and 46 Under 35 U.S.C. § 102(b)
as Unpatentable over Yamauchi (U.S. Patent No. 3,718,140)
Should Be Reversed.

In the Final Office Action, claims 43 - 44 and 46 were rejected under 35 U.S.C. 102(b) as being anticipated by Yamauchi. *11/14/06 Office Action*, p. 4. Yamauchi describes a nursing

bottle nipple adapted for use with a nursing bottle assembly of the collapsible milk bag type. *Yamauchi*, abstract.

Claim 43 was recited above. In the final rejection, the Examiner implied that Yamauchi discloses a catheter because the nursing nipple is a tubular device that is inserted into a body cavity (mouth) to inject fluids (milk). *11/14/06 Office Action*, p. 6. However, it is respectfully submitted that a catheter is a tubular device “designed for insertion into canals, vessels, passageways, or body cavities so as to permit injection or withdrawal of fluids or substances or to maintain the openness of a passageway.” (Webster’s Third International Dictionary, 1986). This definition is entirely consistent with the detailed description and figures of the present invention. In contrast, because Yamauchi describes a nursing nipple, Appellants respectfully submit that the nursing nipple for a baby’s bottle shown in Yamauchi is designed to be grasped between a baby’s lips and controlled thereby and is not suitable for the injection of any substance to or withdrawal of any substance from a body cavity. Injection is defined as driving or forcing fluid into a vessel, cavity or tissue. *Id.* The nursing nipple is simply a device like a straw which allows an infant to draw fluid from a container.

The Examiner stated that Yamauchi discloses a tubular device that is inserted into a body cavity (mouth) to inject fluids (milk). *8/3/07 Examiner’s Answer*, p. 5. However, it is respectfully submitted that an *injection* of milk into a baby’s mouth would be contrary to the teachings of Yamauchi. Because injection is defined as driving or forcing fluid in a vessel, cavity or tissue, to forcibly drive milk into a baby’s mouth would negate all the advantages of the nursing bottle nipple of Yamauchi. Yamauchi stated that an excessive inclination of a bottle occurs, a greater amount of milk may flow out, thereby choking the infant. Those skilled in the art will understand that a forcing of the flow of milk into the mouth of the infant would create a worse scenario. Thus, it is respectfully submitted that the Examiner’s assertion that Yamauchi describes a tubular device that is inserted into a body cavity to *inject* fluids is incorrect. Therefore, Yamauchi does not describe or suggest “an elongate catheter,” as recited in claim 43.

Furthermore, in the final rejection, the Examiner stated that Yamauchi discloses a compound slit “opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter,” as recited in claim 43. However, it is respectfully submitted that the valve of Yamauchi does not open in response to fluid pressure applied thereto. Rather, the valve of Yamauchi is opened by the physical deformation of the nipple as it is squeezed in the mouth of the infant while any suction applied simply aids in maintaining the breast or bottle in the mouth.

It is respectfully submitted that the term “suction” as used in Yamauchi is loosely used to describe the process by which an infant draws milk from a bottle or breast. However, this

process is mechanical and does not rely on fluid pressure to draw liquid from a breast or bottle. As anyone who has milked a cow or seen that a cow can be milked by hand will realize, milk is drawn from the breast by a squeezing, pulling action and the same action is applied by the mouth of a baby or calf to draw the milk naturally from the breast. In fact, the apparatus of Yanauchi is designed to as closely as possible mirror through a bottle the effect of this mechanical action on a breast. Thus, it is respectfully submitted that what is called suckling utilizes suction only to prevent the breast or bottle from slipping from the mouth and, whether applied to a breast or a bottle, fluid pressure is not involved in opening the source of liquid to the baby's mouth. Therefore, Appellants submit that nursing nipples open due to the application of mechanical forces deforming the valve (i.e., by the clamping motion of the baby's jaws) and not due to a fluid pressure differential applied thereto.

Thus, it is respectfully submitted that Yamauchi does not disclose or suggest "an elongate catheter" nor does Yamauchi disclose or suggest a compound slit "opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter," as recited in claim 43 and Appellants respectfully request that the Board overturn this rejection of claim 43 and claims 44 and 46 which depend directly therefrom.

III. The Rejection of Claim 45 Under 35 U.S.C. § 103(a) as Unpatentable over Eaton (U.S. Patent No. 3,303,847) in view of Engelson (U.S. Patent No. 5,798,018) Should Be Reversed.

In the Final Office Action, claim 45 was rejected under 35 U.S.C. 103(a) as obvious over Eaton in view of Engelson. *11/14/06 Office Action*, p. 5. The Examiner stated that Eaton discloses the invention substantially as claimed except for a collar disposed at the distal end of the catheter, but that Engelson discloses a collar used on a similar catheter. *Id.*

Claim 43, from which claim 45 depends, has been recited above. Engelson purports to disclose a catheter used in cardiovascular and endovascular procedures to deliver diagnostic, therapeutic, or vaso-occlusive agents to a target site within a human body accessible by a system of natural passageways within that body. *Engelson*, Abstract. In its entirety, Engelson describes how the distal end of the catheter may reach the target site for injection of the agent, but includes no disclosure of a pressure differential opening a valve for the delivery.

Thus, because claim 45 depends from, and, therefore includes all of the elements recited in claim 43, it is respectfully submitted that neither Eaton nor Engelson, either alone or in combination, discloses or suggests the subject matter of claim 45. Accordingly, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 103(a) of claim 45.

IV. The Rejection of Claim 46 Under 35 U.S.C. § 103(a) as Unpatentable over Eaton (U.S. Patent No. 3,303,847) in view of Yamauchi (U.S. Patent No. 3,718,140) Should Be Reversed.

In the Examiner's Answer, claim 46 was rejected under 35 U.S.C. 103(a) as obvious over Eaton in view of Yamauchi. 8/3/07 *Examiner's Answer*, p. 3. The Examiner stated that Eaton discloses the invention substantially as claimed except for the compound slit being a tricuspid slit, but that Yamauchi discloses a tricuspid slit. *Id.*

Claim 43 from which claim 46 depends has been recited above. As discussed above, Eaton does not disclose or suggest a compound slit "opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter," as recited in claim 43. Also, as discussed above, Yamauchi also does not disclose or suggest this recitation of claim 43.

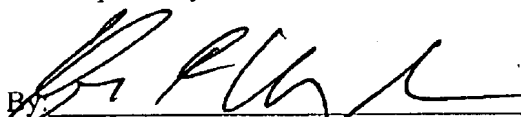
Thus, because claim 45 depends from, and, therefore includes all of the elements recited in claim 43, it is respectfully submitted that neither Eaton nor Yamauchi, either alone or in combination, discloses or suggests the subject matter of claim 45. Accordingly, Appellants respectfully request that the Board overturn the Examiner's rejection under 35 U.S.C. § 103(a) of claim 45.

3. Conclusion

For the reasons set forth above, Appellants respectfully request that the Board reverse all of the final rejections of the claims by the Examiner under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) and indicate that claims 43 - 46 and 61 are allowable.

Respectfully submitted,

Date: October 2, 2007

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Serial No.: 10/277,215
Group Art Unit: 3763
Attorney Docket No.: 10123 - 01901

CLAIMS APPENDIX

43. (Previously Presented) A medical device comprising:
an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter; and
a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen, the compound slit being biased toward a closed position and opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter.
44. (Original) A medical device according to claim 43, wherein the compound slit is disposed on a distal end of the elongate catheter.
45. (Original) A medical device according to claim 44, further comprising a collar disposed at the distal end of the catheter.
46. (Original) A medical device according to claim 43, wherein the compound slit is a tricuspid slit.
61. (Previously Presented) A medical device according to claim 43, wherein the compound slit is configured so that, when the fluid pressure within the lumen exceeds the fluid pressure outside the catheter by a first predetermined amount, flaps of the hemispherical portion formed by the compound slit flex outward away from a longitudinal axis of the catheter to allow fluid within the lumen to exit and when the fluid pressure outside the catheter exceeds the fluid pressure within the lumen by a second predetermined amount, the flaps flex into the lumen to allow fluid outside the catheter to enter the lumen.

Serial No.: 10/277,215
Group Art Unit: 3763
Attorney Docket No.: 10123 - 01901

EVIDENCE APPENDIX

No evidence has been submitted herewith or is relied upon in the present appeal.

Serial No.: 10/277,215
Group Art Unit: 3763
Attorney Docket No.: 10123 - 01901

RELATED PROCEEDINGS APPENDIX

There are no related proceedings and/or decisions which relate to the present appeal.